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10/577,866	10/03/2006	Alexander A. Khromykh	252007	2237

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EXAMINER	
BOESEN, AGNIESZKA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The Amendments filed September 15, 2008 and November 10, 2008 in response to the Office Action of May 14, 2008 are acknowledged and has been entered. Claim 17 was amended. Claims 17-29 are under examination in the present Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 17-23 and 26-29 under 35 U.S.C. 112, first paragraph, **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant amended the claims to recite attenuated Kunjin virus. As discussed in the rejection of record Applicant's claims are enabled for the following embodiments: There are two different suggestions for how Applicant could amend the claims to overcome the present enablement rejection.

1) "A method of **immunizing an animal** including the step of administering an isolated nucleic acid capable of producing an infectious attenuated Kunjin virus to said animal to thereby elicit a **protective immune response to a West Nile virus**."

Or

2) "A method of **inducing an immune response** in an animal including the step of administering an isolated nucleic acid capable of producing an infectious attenuated Kunjin virus to said animal to thereby elicit an **immune response to at least another flavivirus**."

Thus, if Applicant would like to recite the phrase "immunizing an animal" and "protective immune response" Applicant should limit the claims to recite the enabled embodiment of a West Nile virus, as discussed on the record. If Applicant would like to broadly recite "at least another flavivirus", Applicant should amend the claims to change the claim preamble to recite "A method of inducing an immune response" instead of "immunizing" which indicates vaccination, as discussed on the record.

Applicants amendment does not overcome the enablement rejection for essentially the same reasons as discussed on the record in the Office action of May 14, 2008. The recitation of "at least another flavivirus" encompassed a broad genus of viruses for which protective immunization does not currently exist. For example, there is no effective vaccine against hepatitis C virus which belongs to flavivirus family. While cross-protection between some flaviviruses exists, as argued by Applicants, it would have been highly unpredictable to conclude that immunization with infectious attenuated Kunjin virus would confer protection against infection with hepatitic C virus. Applicants have shown that the immunization with infectious attenuated Kunjin virus induces protection against West Nile virus. The skilled artisan would be required to conduct an undue amount of experimentation in order to determine whether immunization with infectious attenuated Kunjin virus would induce protection against other viruses encompassed by the genus of flaviviruses. Applicant's amendment does not overcome the enablement rejection because the claims broadly recite the non-enabled embodiments as discussed above and for this reason the rejection is maintained.

Biological Deposit Requirement

Rejection of claim 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicants explanation with regard to the availability of the NY99 strain. It is noted that present specification contains the information with regard to where the NY99 can be obtained.

Claim Rejections - 35 USC § 102

Rejection of claims 17-29 under 35 U.S.C. 102(a) as being anticipated by Hall et al. (PNAS, September 2, 2003, Vol. 100, p. 10460-10464 in IDS of 10/03/2006) **is withdrawn** in view of Applicants Declaration under 37 CFR § 1.132 filed September 15, 2008. Applicants state that the coauthors Nisbet, Pham, Pyke and Smith made no contribution to the subject matter currently claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 17-23, 26, and 28 under 35 U.S.C. 102(e) as being anticipated by Westaway et al. (US Patent 6,893,866) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that '866 patent describes Kunjin replicon constructs that require the expression of flaviviral structural core prM and E proteins from Semliki Forest Virus for assembly of virus like particles

while the Kunjin virus of the present invention has the ability to produce a full length Kunjin virus genome that can be packaged into virions and can spread thought multiple rounds of infection.

In response, the Office acknowledges that some of the Kunjin virus replicons disclosed in '866 patent comprise proteins from Semliki Forest virus which are required for assembly of the Kunjin replicon into a virus like particle. However the '866 patent discloses other embodiments where the Kunjin virus expresses its own proteins that are sufficient for packaging and replication of infectious Kunjin virus like particles (see claim 1 under b)).

'866 patent does not expressly disclose that the Kunjin virus like particles are attenuated, however, it discloses that the Kunjin virus like particles are "pseudo" infectious (see Example 3). The virus "attenuation" by definition means decreased virulence (ability to cause disease) while maintained ability to infect and replicate in the cells. It is the position of the Examiner that the Kunjin virus **like** particles disclosed by Westaway are attenuated because they are infectious (have the capability to replicate) without causing a disease.

Thus because Westaway discloses methods of generating immune responses comprising administering infectious Kunjin virus like particles, the rejection is maintained.

Claim Rejections - 35 USC § 103

Rejection of claims 17-24, 26-29 under 35 U.S.C. 103(a) as being unpatentable over Anraku et al. (Journal of Virology, April 2002, p. 3791-3799) **is withdrawn** in view of Applicant's arguments and amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejection of claims 17-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-31 of copending Application No. 10/559,146 **is maintained**

Applicants state that Applicants will consider filing terminal disclaimer upon an indication that the rejection is no longer provisional.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Examiner, Art Unit 1648

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643